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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,112	07/27/00	LEE S	JHU1120-11

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EXAMINER	
ANDRES, J	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/628,112	Applicant(s) LEE ET AL.	
	Examiner Janet L Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *4,7,13 and 18-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,8-12 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,8,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I and species election with traverse of SEQ ID NO: 4 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the different species are related and could be searched together. This is not found persuasive because each sequence represents a structurally and functionally distinct entity which is capable of supporting a separate patent, and the search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the databases.

The restriction requirement is made FINAL. Claims 1-33 are pending in this application. Claims 19-33 are withdrawn from consideration as drawn to a non-elected invention. Claims 4-7, 13, and 18 are withdrawn from consideration as drawn to a non-elected species. Claims 1-3, 8-12, and 14-17 are examined in light of the species election of SEQ ID NO: 4.

Specification

2. The use of the trademark SEPHAROSE has been noted in this application (p. 103). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5827733. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope. Instant SEQ ID NO: 4 is identical to SEQ ID NO: 12 of the '733 patent. SEQ ID NO: 2 is identical to SEQ ID NO: 14. Instant claims 1-3 are drawn to a "peptide portion" of these sequences. However, there is no limitation on the size of a portion as defined on p. 18; a portion could encompass the entire molecule. In addition, claim 3 is drawn to portions of polypeptides having a particular sequence. "Having" is the same as "comprising". Thus, the claim included portions of proteins that are longer than SEQ ID NO: 2 or 4, and thus includes proteins comprising the entire sequence.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 8-12, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. These claims are drawn to peptide portions of myostatin. Applicant characterizes the invention on p. 4 as "having or affecting and activity associated with GDF signal transduction". Applicant defines a functional peptide portion on p. 21 as one having the ability to interact with the receptor and affect function, one that can interact with myostatin, or one that can function as a signal peptide. Applicant discloses on p. 20 that the C terminal region of myostatin can interact with its receptor and affect signal transduction, and that the amino terminal pro region can interact with the mature or parent protein. However, the claims encompass activators, inhibitors, binding proteins, cellular localizing signals, and also encompass peptides that interact with different proteins. The specification discloses promyostatin molecules from several species as well as a proteolytic cleavage site that produces the mature protein and the pro domain. The disclosure of these two regions is not sufficient to define the genus of claimed effectors, which encompasses subgenera of molecules having very diverse functions and thus very diverse functional requirements. Applicant has not set forth any structural characteristics or sequences that are required for any particular function. There is no description of the features that would be required for activators, inhibitors, or other molecules having the characteristics set forth on the specification. Since these features are not disclosed, there is no way to determine what portions would possess the defining characteristics. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the peptide portions encompassed: the art teaches only that pro domains are inhibitory. Thus, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in

possession of the claimed genus of peptide portions of promyostatin as defined in the specification.

7. Claims 1-3, 8-12, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the mature myostatin protein and the pro region, does not reasonably provide enablement for peptide portions as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Applicant has described a cleavage site for production of the pro region and the mature myostatin proteins. Based on the teachings in the prior art, this cleavage would be expected to produce an inhibitory pro region and a mature myostatin protein. The claims, however, encompass all "peptide portions", which are defined by Applicant as having many different functions. Applicant has not described the characteristics of these claimed peptide sequences so that one of skill in the art could predictably make and use any "functional" "peptide portion". Applicant has not described the properties or characteristics that are required for any of the functions set forth in the specification. No required sequences or structures that would result in a particular function, or any function, are set forth in the specification. One of skill in the art

would thus not be able to predict what portions would bind receptors or ligands, and what portions would function as inhibitors, activators, or have other properties set forth in the specification. Further, while synthetic and recombinant techniques are available, it is not routine in the art to generate and screen large numbers of peptides where the expectation of obtaining the desired activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in receptor binding and function as an activator or an inhibitor, in the ability to interact with myostatin, or in the ability to act as a signal peptide, in order to practice the invention as claimed without undue experimentation.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, 8-12, and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to "peptide portions" or "functional peptide portions", or "proteolytic fragments". However, there are no limiting definitions such portions or fragments provided so that one of skill in the art would be able to determine what fragments were encompassed and what fragments were not. Further, there is no definition of "functional": what is provided on p. 4 are examples. Thus one of skill in the art would not be able to determine what molecules would meet the limitations of the claims.

10. Claims 16 and 17 are further rejected under 35 U.S.C. 112, second paragraph because claim 16 end with "functional peptide portion of". "Thereof" is presumably intended but as written the claim dose not distinctly point out what the portion is a portion "of".

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
September 24, 2001

Yvonne Eyler

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SUPERVISORY PATENT EXAMINER
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